

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

PAMELA GRAY-WHEELER, et al.,

Plaintiffs,

v.

CIVIL ACTION NO. 2:12-cv-455

ETHICON, INC., et al.,

Defendants.

**MEMORANDUM OPINION AND ORDER**  
**(Motions in Limine)**

Pending before the court are the plaintiffs' Motion in Limine [ECF No. 112], the defendants' Motions in Limine [ECF Nos. 113, 115], and the defendants' Motion for Leave to File a Reply [ECF No. 120].

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 60,000 cases currently pending, approximately 28,000 of which are in this MDL, which involves defendants Johnson & Johnson and Ethicon, Inc. (collectively "Ethicon"), among others.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

*Litigation in Products Liability Cases* 3 (2011). The court seeks the assistance of the parties in completing these tasks by asking the parties to focus on discrete, important, or more relevant matters. Here, the court expected the parties to focus their motions in limine on “highly prejudicial statements in opening or closing statements or questions at trial that, once heard by the jury, cannot be easily cured by an instruction to disregard.” Pretrial Order No. 234, at 5 [2:12-md-2327 ECF No. 2314] (“PTO 234”). The court further cautioned that it would “not provide advisory opinions on the admissibility of evidence a party may offer at trial and [would] summarily deny those motions as premature.” *Id.*

**a. The Plaintiffs’ Motion to Preclude Evidence Relating to the FDA (Motion in Limine No. 1) [ECF No. 112]**

The plaintiffs ask the court to exclude evidence related to the FDA, including the FDA’s 510(k) process, arguing it is impermissibly irrelevant and prejudicial under Federal Rules of Evidence 402 and 403. Pls.’ Mot. Lim. 1–4 [ECF No. 112].

In short, the 510(k) process “does not in any way denote official approval of [a] device.” 21 C.F.R. § 807.97. The process is not focused on whether a device is safe; it is concerned with the device’s equivalence to another device. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996). Because the process does not speak to the safety or efficacy of any product, whether Ethicon products were approved through this process is irrelevant. Even if the 510(k) process were relevant, the court would exclude this evidence under Rule 403. Any kernel of relevance is outweighed by “the very

substantial dangers of misleading the jury and confusing the issues.” *In re C. R. Bard*, 810 F.3d 913, 922 (4th Cir. 2016) (affirming the court’s exclusion of 510(k) evidence).

Put simply, evidence of this sort is inadmissible and, in any event, does not survive a Rule 403 analysis. The court will not belabor the point here as it has already done so on several occasions. *E.g.*, *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 754–56 (S.D. W. Va. 2014). The court **GRANTS in part** the plaintiffs’ Motion in Limine [ECF No. 112] as to Motion in Limine No. 1 and in any other instance where the defendants conceded to the plaintiffs’ Motion. The remainder of the plaintiffs’ Motions in Limine [ECF No. 112] is **DENIED without prejudice**.

**b. The Defendants’ Motion to Exclude the January 2012 “522” Letters and Subsequent FDA Actions (Motion in Limine No. 2) [ECF No. 113]**

The defendants ask the court to exclude evidence of the January 2012 “522” letters and subsequent FDA actions that would have applied to Ethicon devices if they had not been discontinued, arguing it is prejudicial under Federal Rules of Evidence 403 and would require presentation of evidence on a collateral issue. Mem. Supp. Mot. Lim. 3–6 [ECF No. 114]. The plaintiffs do not contest this Motion. Resp. 3 [ECF No. 118]. Indeed, the court has excluded this same evidence on prior occasions. *See, e.g.*, *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, 2014 WL 6680356, at \*1 (S.D. W. Va. Nov. 25, 2014). The court **GRANTS in part** the defendants’ Motion in Limine [ECF No. 113] on this point and in any instance where the plaintiffs concede to the defendants’ Motion; the remainder of the Motion is **DENIED without prejudice**.

**c. The Defendants' Motion to Exclude Evidence of Plaintiff's Allegations of Spoliation [ECF No. 115]**

The defendants have separately filed a motion in limine to exclude evidence related to spoliation. [ECF No. 115]. The plaintiffs have repeatedly alleged that the defendants lost or destroyed documents relevant to this multidistrict litigation. On February 4, 2014, Magistrate Judge Eifert held that the defendants' actions were negligent, not willful or deliberate, and denied the plaintiffs' motions for severe sanctions, such as default judgment, striking of defenses, or offering an adverse instruction in every case. Pretrial Order No. 100, Feb. 4, 2014 [2:12-md-2327 ECF No. 1069] ("PTO 100"). However, Judge Eifert recommended that I allow the plaintiffs "the opportunity to introduce evidence regarding [the defendants'] loss of relevant documents on a case-by-case basis, and, when appropriate, to tender an adverse inference instruction." *Id.* at 42–43. The plaintiffs have since asked Judge Eifert to reconsider PTO 100, claiming that they have discovered new evidence that establishes that the defendants' duty to preserve evidence began earlier than previously thought. *See* Pls.' Request for Clarification and Reconsideration [2:12-md-2327 ECF No. 1099].

While a motion for reconsideration is pending before Judge Eifert, the parties have indicated that they do not desire a ruling on the motion at this time. If and until Judge Eifert rules on the motion to reconsider, her original ruling remains in force and effect. Moreover, the plaintiffs have offered no evidence or argument that

evidence of spoliation will be relevant *in this case*. Therefore, the defendants' Motion in Limine [ECF No. 115] on the issue of spoliation is **GRANTED**.

Accordingly, the defendants' Motion for Leave to File a Reply [ECF No. 120] is **DENIED as moot**.

**d. Conclusion**

The plaintiffs' Motion in Limine [ECF No. 112] is **GRANTED in part** as to Motion in Limine No. 1 and any other conceded motion therein; the remainder of the Motion is **DENIED without prejudice**. The defendants' Motion in Limine [ECF No. 113] is **GRANTED in part** as to Motion in Limine No. 2 and any other conceded motion therein; the remainder of the Motion is **DENIED without prejudice**. The defendants' Motion to Exclude Evidence of Plaintiff's Allegations of Spoliation [ECF No. 115] is **GRANTED**. The defendants' Motion for Leave to File a Reply [ECF No. 120] is **DENIED as moot**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: January 20, 2017



JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE